

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460



OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Antimicrobial Division

May 17, 2016

**MEMORANDUM**

**SUBJECT:** Acute Toxicity Review for EPA Reg. No. 1677-ELU  
Product Name: (HSP2O) SPX  
DP Barcode: 431606

**TO:** Demson Fuller / Benjamin Chambliss  
PM Team # 32

**FROM:** Boris S. Yurchak, Chemist  
Product Science Branch, CT Team  
Antimicrobials Division (7510P)

**THRU:** Karen P. Hicks, CT Team Leader  
Product Science Branch  
Antimicrobials Division (7510P)

**APPLICANT:** Ecolab, Inc  
**Action code:** (A540) New product; non-fast track  
**Due out date:** Late to CTT

**PRODUCT FORMULATION FROM LABEL:**

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Sodium hypochlorite	3.9
<u>Other Ingredient(s)</u>	<u>96.1</u>
TOTAL	100.0

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**DP BARCODE:** 431606

**MRID(s):** 49741019, 49741020, 49741021, 00007381, 00007580, 00007560

**SUBJECT:** XHC-E

**REG. NO. OR FILE SYMBOL:** 1677-ELU

**DOCUMENT TYPE:** Acute Toxicity Review

**Manufacturing-use** ☐ **OR** **End-use Product** ☒

**INGREDIENTS:**

<u>PC Code(s)</u>	<u>CAS Number(s)</u>	<u>Active Ingredient(s)</u>
014703	7681-52-9	Sodium hypochlorite

**TEST LAB:** N/A

**SUBMITTER:** Ecolab, Inc

**GUIDELINE(s):** 870.1100, 870.1200, 870.1300, 870.2400, 870.2500, 870.2600

**COMMODITIES:** N/A

**REVIEWER:** Boris S. Yurchak **ORGANIZATION:** AD/PSB/CTT

**APPROVER:** Karen P. Hicks **APPROVED DATE:** \_\_\_/\_\_\_/2016

**COMMENT:** This product is for food and non-food use

## BACKGROUND:

To support the registration of the subject product, XHC-E, EPA Reg. No. **1677-ELU**, the registrant suggested the “cite all” option to select by the Agency 3 acute toxicity studies 81-1 thru 81-3 that are appropriate for the subject product. As per the Agency request, dated 4/11/2016, the registrant provided MRID #s 00007381 and 00007580 for 81-1, 00007381 for 81-2, 00007560 and 00007580 for 81-3 in Data Matrix, dated 5/5/2016. For studies 81-4 thru 81-6, the registrant provided waiver requests in MRID #s 497410-19, -20 and -21, respectively. The product is a disinfectant for use on hard non-porous inanimate surfaces.

The data package also included:

1. Cover letter from Registrant to EPA, dated 11/03/2015
2. Application for pesticide registration, Form 8570-1
3. Transmittal document, dated 11/03/2015
4. Basic Confidential Statements of Formula (CSF), dated 10/30/2015
5. Proposed label, punch dated 10/28/2015

## FINDINGS:

1. Waiver requests for Primary Eye Irritation (81-4), Primary Dermal Irritation (81-5) and Dermal Sensitization (81-6) are based on the fact of high value of pH that makes the product corrosive to skin. The waivers are granted.
2. MRID #s 00007381, 00007580 and 00007560 provided for studies 81-1, 81-2 and 81-3 were not found in the Agency database. The studies are considered data gaps.

The acute toxicity profile for EPA Reg. No. **1677-ELU** is currently:

GRN	Study	MRID	Toxicity Category	Status
81-1	Acute Oral Toxicity	00007381		Data Gap
		00007580		Data Gap
81-2	Acute Dermal Toxicity	00007381		Data Gap
81-3	Acute Inhalation Toxicity	00007560		Data Gap
		00007580		Data Gap
81-4	Primary Eye Irritation	49741019	I	waived
81-5	Primary Dermal Irritation	49741020	I	waived
81-6	Dermal Sensitization	49741021	Non a sensitizer	waived

## CONCLUSION:

The requirements under Guidelines 81-1 thru 81-3 are considered data gaps. The acute toxicity requirements have not been satisfied for the subject product EPA Reg. No. 1677-ELU.